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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/844,311      | 04/27/2001  | Yung T. Huang        | DHI-06207           | 1225             |

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SAN FRANCISCO, CA 94105

EXAMINER

FOLEY, SHANON A.

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1648

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DATE MAILED: 04/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/844,311

Applicant(s)

HUANG, YUNG T.

Examiner

Shanon Foley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 February 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 15-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>6</u> . | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election without traverse of group I in Paper No. 10 is acknowledged.

Applicant's traversal of SEQ ID NO: 1 and SEQ ID NO: 3 is also acknowledged and is found persuasive. The restriction requirement between SEQ ID NO: 1 and 3 is withdrawn.

Claims 1-18 are pending, claims 15-18 are withdrawn from consideration due to a non-elected invention and claims 1-14 are under consideration.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 6, 7 and 11-14 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is apparent that BGMK-hDAF cells are required to practice the claimed invention because they are a necessary limitation for the success of the invention as stated in the claims. As a required element it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification, or otherwise readily available to the public. If it is not so obtainable or available, a deposit of the claimed cell line in an acceptable depository may satisfy the enablement requirements of 35 U.S.C. § 112, first paragraph. See 37 CFR 1.802. One cannot practice the claimed invention without the claimed cell line. One cannot determine

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whether a cell line has the necessary characteristics without access to the cell line claimed, BGMK-hDAF. Therefore, access to BGMK-hDAF is required to practice the invention. In the paragraph bridging pages 17 and 18, the specification states that BGMK-hDAF “will be deposited”. There is also a working example demonstrating the construction of BGMK-hDAF on pages 38-40. However, reference to a future deposit of the claimed cell line does not guarantee public availability for the skilled artisan to compare whether a cell line produced by the method in example 1 would share the same characteristics with BGMK-hDAF recited in claim 1.

Deposit of BGMK-hDAF cells in a recognized deposit facility would satisfy the enablement requirements of 35 U.S.C. 112., because the cells would be readily available to the public to practice the invention claimed, see 37 CFR 1.801- 37 CFR 1.809.

If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 CFR 1.808.

If a deposit is not made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating

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that the deposit has been made at an acceptable depository and that the following criteria have been met:

(a) during the pendency of this application, access to the invention will be afforded to one determined by the Commissioner to be entitled thereto;

(b) all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained for a term of at least thirty (30) years and at least five (5) years after the most recent request for the furnishing of a sample of the deposited material;

(d) a viability statement in accordance with the provisions of 37 CFR 1.807; and

(e) the deposit will be replaced should it become necessary due to inviability, contamination or loss of capability to function in the manner described in the specification.

In addition, the identifying information set forth in 37 CFR 1.809(d) should be added to the specification. See 37 CFR 1.803 - 37 CFR 1.809 for additional explanation of these requirements.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4 and 6-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scholl et al. (US 6,168,915) and Powell et al. (Journal of General Virology. 1998; 79: 1707-1713).

Claim 1 is drawn to a cell line designated BGMK-hDAF. Claims 2-4 and 6-8 are drawn to a buffalo green monkey kidney cell line that has increased sensitivity to one or more enteroviruses or permissiveness to echovirus-6 or echovirus-11. Claims 11 and 13 are drawn to a composition comprising the cell lines comprising and established from BHK-hDAF. Finally, claims 9, 10, 12 and 14 are drawn to the compositions comprising a cell type other than BHK-hDAF.

Scholl et al. teach methods using compositions comprising a first cell type and a second cell type to detect the presence of enterovirus in a sample. The first cell type is buffalo green monkey kidney cells that are susceptible to enterovirus infection and the second cell type is A549 cells, see column 5, lines 16-18 and 25-35, column 8, lines 30-34, column 11, lines 57-62, column 27, line 35 to column 28, line 61, and claims 11-14. Scholl et al. does not teach increased susceptibility to enteroviruses of a cell line expressing the human decay accelerating factor.

However, Powell et al. teach increased susceptibility and permissiveness of echoviruses, including EV6, to cells recombinantly expressing the decay accelerating factor (DAF or CD55). See the paragraph bridging pages 1711-1712.

One of ordinary skill in the art at the time the invention was made would have been motivated to express DAF taught by Powell et al. in the buffalo green monkey cell lines of Scholl et al. to detect enterovirus haemagglutinating strains that use DAF for cell surface attachment and entry. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation for producing the claimed invention because both Scholl et al. and Powell et al. use cells expressing recombinant genes to detect the presence of viruses. One

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of ordinary skill in the art at the time the invention was made would also have had a reasonable expectation for producing the claimed invention because Scholl et al. teach that buffalo green monkey cells are susceptible to enterovirus infection and Powell et al. teach that cells expressing DAF are permissive to infection by haemagglutinating enterovirus strains. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, absent unexpected results to the contrary.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Scholl et al. and Powell et al. as applied to claims 1-4 and 6-14 above, and further in view of Spiller et al. (Journal of Infectious Diseases. 2000; 181: 340-343) with the sequence alignment of SEQ ID NO: 1 with GenEmbl database accession no. M15799 of Medoff et al. (PNAS. 1987; 84 (7): 2007-2011), or in the alternative, Spiller et al. with the sequence alignment of SEQ ID NO: 3 with GenEmbl database accession no. M30142 of Caras et al. (Nature. 1987; 325 (6104): 545-549).

The claim is drawn to specific sequences, SEQ ID NOs: 1 or 3, of the human decay accelerating factor.

See the teachings of Scholl et al. and Powell et al. above. The references do not teach SEQ ID NOs: 1 or 3.

However, SEQ ID NOs: 1 or 3 of the human decay accelerating factor are known in the art, see the sequence alignments provided.

One of ordinary skill in the art at the time the invention was made would have been motivated to transfect the buffalo green monkey cell lines of Scholl et al. with either sequence of the human decay accelerating factor known in the art to detect the presence of enterovirus haemagglutinating strains that use DAF for cell surface attachment and entry taught by Powell et

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al. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation for detecting the presence of enteroviruses using either SEQ ID NO: 1 or SEQ ID NO: 3 because both of the sequences are human DAFs and Spiller et al. teach that echoviruses and cocksackie B viruses almost exclusively bind to human DAF sequences, see Table 1 on page 343. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, absent unexpected results to the contrary.

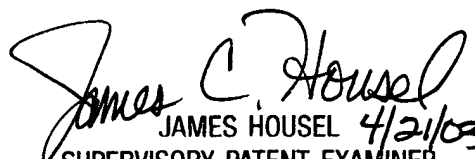
### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon Foley whose telephone number is (703) 308-3983. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (703) 308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4426 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

  
Shanon Foley  
April 15, 2003

  
JAMES HOUSEL 4/21/03  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600